

**EXHIBIT C**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SMITH KLINE & FRENCH	)	
LABORATORIES LIMITED and	)	
SMITHKLINE BEECHAM	)	
CORPORATION d/b/a	)	
GLAXOSMITHKLINE,	)	
	)	
Plaintiff,	)	Civil Action No. 05-197-GMS
	)	
v.	)	
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

**PLAINTIFF GLAXOSMITHKLINE'S RESPONSES TO  
DEFENDANT'S FIRST SET OF INTERROGATORIES**

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Plaintiffs SmithKline and French Laboratories, Ltd. and SmithKline Beecham Corporation, doing business as GlaxoSmithKline ("GSK"), hereby respond to the First Set of Interrogatories from Defendant Teva Pharmaceuticals USA, Inc. ("Teva") as follows:

**GENERAL OBJECTIONS**

GSK incorporates by reference, as if fully set forth herein, the General Objections that GSK has made in its Responses and Objections to Defendant's First Set of Requests for Production of Documents and Things.

**SPECIFIC RESPONSES AND OBJECTIONS**

Subject to the specific objections set forth below, and specifically incorporating each of the foregoing General Objections into each Specific Response below, and without waiving said objections and responses, GSK responds as follows:

**Interrogatory No. 1:**

Identify each claim of the Patents-In-Suit that Plaintiffs assert Teva's ANDA infringes or will infringe, and for each such asserted claim, identify the claim terms Plaintiffs contend require construction and provide Plaintiffs' construction of said terms, including evidence in support thereof.

**Response:**

GSK objects to this interrogatory as premature. Because discovery has only just begun, GSK may in the future add or delete the claims of the Patents-In-Suit that GSK believes are infringed or will be infringed by Teva's ANDA, identify claim terms that may require construction, or modify the evidentiary support cited in this interrogatory response. As with all its other interrogatory responses, GSK reserves the right to supplement and/or amend the following response during the course of this litigation.

Subject to and without waiving the foregoing objections and its General Objections, GSK responds as follows:

GSK asserts that Teva's ANDA infringes at least Claims 1-5 and Claims 8-10 of U.S. Patent No. 4,452,808 (the "'808 patent") and all three claims (Claims 1, 2, and 3) of U.S. Patent No. 4,824,860 (the "'860 patent"). Teva's ANDA filing constitutes evidence of infringement.

**Interrogatory No. 2:**

Identify each person involved in the prosecution of the Patents-In-Suit and all Related Applications, including foreign counterparts, and for each such person describe in detail their involvement with respect to each particular patent or patent application.

**Response:**

GSK objects to this interrogatory on the basis that the identification of "each" person and the role of "each" person involved in the prosecution of the Patents-in-Suit and their foreign counterparts would be unduly burdensome because GSK prosecuted the Patents-In-Suit, Related Applications, and their foreign counterparts in at least forty countries. Local counsel for the foreign prosecutions included numerous law firms, patent agents, and attorneys worldwide. GSK further objects to this interrogatory to the extent that the information sought by this interrogatory is protected from disclosure by the attorney-client privilege and/or attorney work product doctrine.

GSK also objects to this interrogatory to the extent that it requests information that is not relevant or reasonably calculated to lead to the discovery of admissible evidence.

GSK further objects to this interrogatory because it contains two subparts, each of which, pursuant to Local Rule 26.1(b), counts as a separate interrogatory.

Subject to and without waiving the foregoing objections and its General Objections, GSK presently believes that the following individuals had some involvement in drafting the United States patent application for the '808 and '860 patents and communicating with the United States Patent and Trademark Office (the "USPTO") during the prosecution of those patents:

The '808 Patent

- William H. Edgerton

The '860 Patent

- Vincent L. Fabiano
- Peter J. Giddings, Ph. D.

Additional individuals may be identified from documents that GSK will produce or make available in responsive to Teva's discovery requests.

Interrogatory No. 3:

For each claim of the Patents-In-Suit, identify the alleged inventor(s) of the subject matter of the claim, and describe with particularity the facts and circumstances surrounding any alleged conception, reduction to practice, and/or claim to diligence from conception to reduction to practice, including, separately for each claim, identification of all relevant dates, locations, witnesses, documents, and things concerning such alleged conception, reduction to practice and/or diligence.

**Response:**

GSK objects to this interrogatory on the grounds that it is unduly burdensome to identify "all" relevant dates, locations, witness, documents, and things concerning the inventive process. This request is also premature to the extent that discovery has just begun and additional information may become available during the discovery process that relates to the questions posed in this interrogatory. GSK further objects to this interrogatory because it contains three subparts, each of which, pursuant to Local Rule 26.1(b), counts as a separate interrogatory.

Subject to and without waiving the foregoing objections and its General Objections, GSK responds as follows:

The '808 Patent

The '808 patent lists Gregory Gallagher as the sole inventor of the claims set forth in that patent. At the time of the invention, Gallagher was an employee at SmithKline Beckman ("SKB"). At least as early as 1982, Gallagher conceived of the idea of removing the *para*-OH group from the aromatic ring of 4-aminoalkyl-7-hydroxy-2(3H)-indolone compounds.

At least as early as 1982, Gallagher synthesized ropinirole, which lacks the *para*-OH group of the corresponding 4-aminoalkyl-7-hydroxy-2(3H)-indolone compound, thereby reducing to practice the invention claimed in the patent.

The '860 Patent

The '860 patent lists Dr. David A. A. Owen as the sole inventor of the claims set forth in that patent. Dr. Owen, a scientist who worked at Smith Kline & French ("SK&F") in the United Kingdom, conceived of the claimed subject matter of the '860 patent in or around 1986.

After ropinirole was synthesized in 1982, Dr. J. Paul Hieble and other researchers at SKB's Philadelphia office tested ropinirole and began developing ropinirole as a cardiovascular drug.

In 1985, the development work relating to ropinirole was transferred to the Welwyn Garden City office of SK&F. Dr. Owen was the Director of the Pharmacology Division at the time of the transfer and became a project team member for ropinirole. Based on tests of ropinirole conducted under his direction, Dr. Owen determined that ropinirole caused central nervous system ("CNS") activity and conceived of using ropinirole to treat central nervous system disorders including Parkinson's disease. Further CNS evaluations performed by SK&F

in Welwyn and by researchers at the University of Bradford engaged by SK&F further demonstrated ropinirole's potential as an anti-Parkinson's agent.

Persons having knowledge of these events are listed in response to Interrogatory Number 9. Pursuant to Fed. R. Civ. P. 33(d), GSK will produce or make available records sufficient to support the response to this interrogatory as set forth above.

**Interrogatory No. 4:**

Identify all opinions, studies, tests, comparisons, analyses, examinations, or investigations performed by or on behalf of Plaintiffs prior to the filing of this Action concerning the claimed subject matter of any of the Patents-In-Suit.

**Response:**

GSK objects to this interrogatory as overbroad and unduly burdensome insofar as it seeks identification of "all" opinions, studies, tests, comparisons, analyses, examinations, or investigations concerning the subject matter claimed in the Patents-In-Suit regardless of the date of such documentation or whether such information is relevant to the issues in this case. As a pharmaceutical drug, ropinirole underwent extensive testing to determine its therapeutic value and to satisfy the rigorous testing requirements of the FDA and other foreign regulatory agencies. The vast majority of this testing is not relevant to the issues in this litigation, and requests for this information are not reasonably calculated to lead to the discovery of admissible evidence.

GSK further objects to this interrogatory to the extent that the information sought by this interrogatory is protected from disclosure by the attorney-client privilege and/or attorney work product doctrine.

Subject to and without waiving the foregoing objections and its General Objections, GSK responds that, pursuant to Fed. R. Civ. P. 33(d), GSK will produce or make available records generated prior to the issuance of the Patents-In-Suit concerning the conception, reduction to practice, and experiments using the inventions claimed in the Patents-In-Suit to the extent they exist in GSK's files and can be located from a reasonable search.

**Interrogatory No. 5:**

Identify any actual, proposed, or requested assignments, licenses, covenants, security interests, or other present or future interests to any of the Patents-In-Suit (alone or in combination with other patents), the claimed subject matter of the Patents-In-Suit, or any foreign counterparts to the Patents-In-Suit.

**Response:**

GSK objects to this interrogatory to the extent that it requires GSK to divulge "proposed" or "requested assignments, licenses, covenants, security interests, or other present or future interests" relating to ropinirole or its use in Parkinson's disease. Any such future proposal or unfulfilled request would not be relevant to the current litigation unless and until the transaction were to be completed.

Subject to and without waiving the foregoing objections and its General Objections, GSK thus will limit its response to identifying existing assignments relating to ropinirole. GSK will supplement and/or amend its response to this interrogatory during the course of this litigation if necessary.

GSK identifies the following assignments relating to the '808 and '860 patents:

- On June 5, 1984, the '808 patent was duly and legally issued to Gregory Gallagher Jr. and was assigned on its face to SmithKline Beckman Corporation. In 1989,



SmithKline Beckman Corporation changed its name to SmithKline Beecham Corporation. In 2000, after GlaxoSmithKline plc acquired its corporate parent SmithKline Beecham plc, SmithKline Beecham Corporation began doing business as GSK. SmithKline Beecham Corporation d/b/a GSK has all rights and title to the '808 patent.

- On April 25, 1989, the '860 patent was duly and legally issued to Dr. David A. A. Owen, Ph.D. and was assigned on its face to Smith Kline & French Laboratories Limited. In 2000, after GlaxoSmithKline plc acquired its corporate parent SmithKline Beecham plc, Smith Kline & French Laboratories Limited began doing business as GSK. Smith Kline & French Laboratories Limited d/b/a GSK has all rights and title to the '860 patent.

Subject to and without waiving the foregoing objections and its General Objections and pursuant to Fed. R. Civ. P. 33(d), GSK will produce or make available non-privileged documents from which additional responsive information, if any, relevant to this litigation may be derived, to the extent that they exist in GSK's files and can be located through a reasonable search.

**Interrogatory No. 6:**

Identify, by trade name and New Drug Application number (or foreign regulatory equivalent identifying number), all products marketed or sold, presently or in the past, that use ropinirole or ropinirole hydrochloride as an active ingredient, and for each such product identify, the manufacturer(s) and marketer(s) of the product, how the product was administered, the dates the product was marketed, and which, if any, claims of the Patents-In-Suit Plaintiffs contend cover the product, the use of the product, or the process of manufacturing the product.

**Response:**

GSK objects to this interrogatory as overbroad in that it requests the identification of all products that use ropinirole or ropinirole chloride regardless of their indication. GSK further objects to this interrogatory because it is not reasonably calculated to lead to the discovery

admissible evidence. GSK further objects to this interrogatory because it contains five subparts, each of which, pursuant to Local Rule 26.1(b), counts as a separate interrogatory.

Subject to and without waiving the foregoing objection and its General Objections, GSK states that GSK received approval from the FDA (NDA No. 20-658) for Requip<sup>®</sup> tablets containing ropinirole hydrochloride in strengths of Eq 0.25 mg base, Eq 0.5 mg base, Eq 1 mg base, Eq 2 mg base, Eq 3 mg base, Eq 4 mg base, and Eq 5 mg base.

**Interrogatory No. 7:**

To the extent Plaintiffs allege that there exist any secondary considerations of nonobviousness within the meaning of *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), with respect to any Asserted Claim of the Patents-In-Suit, including, but not limited to, any allegation of commercial success, long-felt need, failure of others, or “unexpected results” (within the meaning of *In re Geisler*, 116 F.3d 1465, 1469-70 (Fed. Cir. 1997)), state in detail and with particularity the bases for the allegation and identify all documents, things, witnesses or other evidence on which Plaintiffs rely or may rely in support of such allegation(s).

**Response:**

GSK objects to this interrogatory as premature. The Patents-In-Suit are, and are presumed to be, valid. 35 U.S.C. § 282. Unless and until Teva demonstrates, by clear and convincing evidence, that the '808 and '860 patents would have been obvious to one of skill at the time of the respective inventions, GSK is under no obligation to provide any evidence of nonobviousness, including evidence relating to secondary considerations of nonobviousness.

GSK objects to this interrogatory as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it calls for “all

documents, things, [and] witnesses" regarding the subject matter of the interrogatory. GSK further objects to this interrogatory because it contains two subparts, each of which, pursuant to Local Rule 26.1(b), counts as a separate interrogatory.

Subject to and without waiving the foregoing objections and its General Objections, GSK responds as follows:

The synthesis of ropinirole produced surprising and unexpected results in that one of ordinary skill in the art would not have expected ropinirole or other claimed compounds, each of which lacks a 7-hydroxy group, to have dopamine agonist activity. In addition, others tried and failed to develop a compound that had the favorable pharmacological profile demonstrated by the claimed compounds of the '808 patent. Furthermore, as indicated by its ANDA, Teva has copied or intends to copy the compounds disclosed in the '808 patent.

The discovery that ropinirole could treat Parkinson's disease was surprising and unexpected because this compound had previously been reported as not producing the central behavioral effects often seen with dopamine agonists. Dr. Owen realized that, contrary to expectations, ropinirole had CNS effects and could be a successful treatment for central nervous system disorders such as Parkinson's disease. In addition, ropinirole's use for Parkinson's disease satisfied a long-standing clinical need for treatments that targeted only certain dopamine receptors and therefore created fewer side effects. Ropinirole showed distinct unexpected advantages over known dopamine agonists in having been found to have additional effects on the central nervous system, namely, anti-depressant and anxiolytic effects, and minimal liability to cause dyskinesia. Ropinirole's more selective binding activity and fewer side effects therefore expanded the treatment options for Parkinson's patients. Furthermore, as indicated by its ANDA, Teva has copied or intends to copy the compounds disclosed in the '860 patent.

Products sold by GSK embodying the inventions claimed in the '808 and '860 patent have enjoyed substantial commercial success.

Subject to and without waiving the foregoing objections and its General Objections, and pursuant to Fed. R. Civ. P. 33(d), GSK will produce or make available non-privileged documents from which additional responsive information, if any, relevant to this litigation may be derived, to the extent that they exist in GSK's files and can be located through a reasonable search.

**Interrogatory No. 8:**

State whether any of the Patents-In-Suit or Related Applications have ever been asserted in or been the subject of any litigation, arbitration, negotiation, mediation, administrative proceeding (including reissue, reexamination, interferences, and oppositions), or otherwise the subject of an infringement, enforceability, or invalidity assertion by or against a third party, and describe in detail any such circumstances including the concerned patent or application, parties, and court, tribunal or agency (if appropriate), and the two persons most knowledgeable concerning the circumstances.

**Response:**

GSK objects to this request as overly broad in that it seeks information related to other proceedings, regardless of whether this information is relevant to the issues in this case. GSK objects to this interrogatory because it contains two subparts, each of which, pursuant to Local Rule 26.1(b), counts as a separate interrogatory. As with all its other interrogatory responses, GSK reserves the right to supplement and/or amend its response to this interrogatory as necessary during the course of this litigation.

Subject to and without waiving the foregoing objections and its General Objections, GSK responds that the Patents-In-Suit or Related Applications have not been asserted in litigation, arbitration, negotiation, mediation, administrative proceeding (including reissue, reexamination, interferences, and oppositions), or otherwise the subject of an infringement, enforceability, or invalidity assertion by or against a third party.

**Interrogatory No. 9:**

Identify the name and last known address of each person reasonably likely to have information that bears significantly on the claims and defenses in the present action (including all claims and defenses to Teva's counterclaims), identifying the subjects of the information; and identify by production number or other specific reference all documents, data, compilations, and tangible things in the possession, custody, or control of that person that are likely to bear significantly on the claims and defenses in the present action.

**Response:**

Because discovery has just begun, GSK objects to this interrogatory as premature and overbroad to the extent that it requires, at this early stage, the identification and address of "each" person and "all" of such person's documents, compilations and tangible things significantly bearing on the claims and defenses in the present action. GSK objects to the request for identification of "all" documents as overly broad and unduly burdensome. GSK further objects to this interrogatory to the extent that the documents, compilations, and tangible things requested are not within the possession, custody, or control of GSK or are protected from disclosure by the attorney-client privilege and/or attorney work product doctrine. Finally, GSK objects to this interrogatory because it contains three subparts, each of which, pursuant to Local

Rule 26.1(b), counts as a separate interrogatory. As with all its other interrogatory responses, GSK reserves the right to supplement and/or amend its response to this interrogatory as necessary during the course of this litigation.

Subject to and without waiving the foregoing objections and its General Objections, GSK responds as follows:

The following persons have been identified by GSK as potentially having information that bears on the present action.

Name	Subject of Information	Last Known Address
Brenda Costall, Ph.D.	Aided in testing the effect of ropinirole on the central nervous system	School of Pharmacy, University of Bradford Bradford West Yorkshire BD7 1DP, UK
William H. Edgerton	Assisted in prosecution of '808 patent	1660 Colonist Square SW Ocean Isle Beach, NC 28469
Roger J. Eden	Involved in pharmacological testing of ropinirole in the United Kingdom	242 Daniells Welwyn Garden City, Herts AL7 1QQ United Kingdom
Vincent L. Fabiano	Assisted in prosecution of '860 patent	Ranbaxy Pharmaceuticals Inc. 600 College Road East Suite 2100 Princeton, NJ 08540
Gregory H. Gallagher	Named inventor of the '808 patent	7032 Harrington Lane Bradenton, FL 34202
Peter J. Giddings, Ph.D.	Assisted in prosecution of '860 patent	GlaxoSmithKline Services Unlimited 980 Great West Road Brentford Middlesex TW8 9GS

Carol Harvey, Ph.D.	A project team leader for drug development of ropinirole in the United Kingdom	GlaxoSmithKline 709 Swedeland Road King of Prussia, PA 19406
J. Paul Hieble, Ph.D.	Involved in the pharmacological testing of ropinirole in the United States	GlaxoSmithKline 709 Swedeland Road King of Prussia, PA 19406
William F. Huffman, Ph.D.	Supervisor of Gregory H. Gallagher	GlaxoSmithKline 709 Swedeland Road King of Prussia, PA 19406
David A. A. Owen, Ph.D.	Named inventor of the '860 patent	Coppice Farm Stanton upon Hine Heath Shrewsbury Shropshire SY4 4ET
Annette Wright	Involved in pharmacological testing of ropinirole in the United Kingdom	51 Ladder Hill Wheatley Oxford OX33 1SX

**Interrogatory No. 10:**

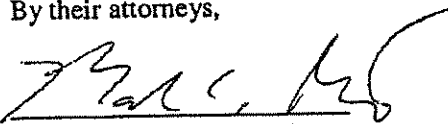
Identify each witness that Plaintiffs intend to call at any hearing or trial and the subject matter of the testimony of each such witness, including the facts to which such persons are expected to testify and any exhibits expected to be used in connection with the testimony, and, if testifying as an expert: the opinions to which such expert(s) is expected to testify; the person's qualifications, and all documents authored or contributed to and all presentations given or participated in by such person; all prior hearing, deposition, and trial testimony by such person; a report of the expert's opinion; and all documents and other information relied upon or used by the witness in preparing for his or her testimony and report.

**Response:**

GSK objects to this request as premature because discovery has just begun, depositions have not been taken, expert reports are not due, and no claim construction has been adopted by the Court. Additionally, GSK objects to this inquiry to the extent that the information requested is protected from disclosure by the attorney-client privilege and/or attorney work product doctrine. GSK further objects to, as overbroad and duly burdensome, Teva's requests for "all documents authored or contributed to and all presentations given or participated in by" and "all prior hearing, deposition, and trial testimony by" GSK's expert witnesses. Such requests are not limited to any particular subject matter or any particular date range, and, to the extent such information is publicly available, can be located just as easily by Teva as GSK. Finally, GSK further objects to this interrogatory because it contains eight subparts, each of which, pursuant to Local Rule 26.1(b), counts as a separate interrogatory.

Subject to and without waiving the foregoing objections and its General Objections, GSK will provide information regarding identification of fact and expert witnesses in accordance with the deadlines for discovery and trial set forth by the Court.

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